

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	C.A. No. 21-1015 (LPS)
v.)	
)	REDACTED - PUBLIC VERSION
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	

**SAREPTA’S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE AND
DISMISS CLAIMS II-III OF NIPPON SHINYAKU’S FIRST AMENDED COMPLAINT**

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I. CLAIM II IS DEFICIENT ON ITS FACE AND SHOULD BE DISMISSED

In response to Sarepta’s first motion to dismiss Claim II (D.I. 33), Nippon Shinyaku (“NS”) attempted to cure its deficient noninfringement allegations by stating in the Amended Complaint: “*Nippon Shinyaku alleges that it does not infringe because the UWA Patents are invalid. A party cannot be liable for infringement of an invalid claim.*” D.I. 39 at ¶¶ 89-106 (citing *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015)). Sarepta’s current Rule 12(b)(6) opening brief (D.I. 54 (“Sarepta Br.”)) demonstrated that NS’s reliance on *Commil* for its noninfringement position was incorrect and refuted by the holding of *Commil*. Sarepta Br. at 7-11. NS now abandons this argument and no longer even mentions *Commil* in its response. *See* D.I. 64 (“NS Resp.”).

Nothing else in NS’s answering brief counters Sarepta’s sound reasons for dismissing Claim II’s request for declaratory judgment (“DJ”), *see id.* at 16-20, and the Court should find the new pleading also insufficient under Rule 12(b)(6), *see* Sarepta Br. at 7-11. NS’s brief is most telling for where it ends up—a final section suggesting that NS should be able to amend its pleading yet again. NS Resp. at 20. NS foreshadows further amendments for a reason: Its Amended Complaint is still plainly deficient under controlling case law from this Court, notwithstanding that Sarepta identified a lack of claim-specific pleading the first time around. *See* D.I. 33 at 13-16. NS fails to address the substance of *Princeton Digital Image Corp. v. Konami Digital Entertainment Inc.*, No. 12-1461-LPS-CJB, 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017), a case directly on point and raised extensively by Sarepta to highlight the deficiencies of NS’s Claim II. Sarepta Br. at 2, 7, 9-11. There, the Court found that unsupported allegations that certain products did not meet the limitations of the asserted patent claims were not enough to plead a DJ claim of noninfringement without more. *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (entitlement to relief “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do”).

Contrary to the case law that even NS cites, the Amended Complaint still does not identify “one of its products *and* the claim elements from [the] asserted patents that it believes are missing.”¹ Compare NS Resp. at 17 (quoting *Rain Gutter Pros, LLC v. MGP Mfg., LLC*, 55 F. Supp. 3d 1330, 1336 (W.D. Wash. 2014)), with D.I. 39, ¶¶ 77-89. The Amended Complaint is thus facially insufficient to meet NS’s obligation under Rule 8 “to set forth factual allegations showing *how* each accused product or service specifically does not meet at least one claim limitation.” *Comcast Cable Commc’ns, LLC v. OpenTV, Inc.*, 319 F.R.D. 269, 273 (N.D. Cal. 2017) (dismissing noninfringement claim because “complaint must go beyond only stating in conclusory terms that each accused product or service meets the elements of non-infringement”). NS’s Amended Complaint has no facts regarding the way in which the VILTEPSO[®] product allegedly does not meet one or more limitations of any particular claim. D.I. 39, ¶¶ 2, 77-89. Even as amended, NS continues to seek an open-ended advisory opinion of noninfringement with respect to all three UWA Patents. *See id.*

NS only now suggests a possible theory of noninfringement in its *briefing*, NS Resp. at 19, but not in its *pleading*. Specifically, NS states in its Response that:

At least certain claims of the UWA Patents cover a “method for treating a patient with [DMD]” that require “administering to the patient an antisense oligonucleotide.” D.I. 2, Ex. K at Claim 1. As Nippon Shinyaku does not administer VILTEPSO[®] but is instead involved in the marketing and sale of VILTEPSO[®], it cannot directly infringe certain claims of the UWA Patents requiring a step of “administering to the patient an antisense oligonucleotide.”

¹ NS modifies this text in *Rain Gutter* to read “[the],” but the original language is as follows: “In support of these claims, RGP has identified one of its products and the claim elements from both asserted patents that it believes are missing. The Court finds this adequate to allege plausible non-infringement claims against MGP” 55 F. Supp. 3d. at 1336 (emphases added). Thus, *Rain Gutter* noted that for *both* patents declaratory judgment jurisdiction had been shown. *See id.* Not so here, where only one UWA patent is identified at the level of the claims, albeit only in the NS brief. *See* NS Resp. at 19-20.

Id. These noninfringement allegations appear nowhere in the Amended Complaint, however—even after amending, the responsive brief is the first time NS has raised any patent or claim specifically under Claim II. *See* D.I. 39, ¶¶ 2, 77-89. This is not enough for at least two reasons.

First, as to procedure, the *Bender* case cited by NS dismissed the count at issue because a court “is limited to basing a 12(b)(6) determination on the facts alleged in the operative pleading” and will not consider allegations that are only included in opposition briefs. *Bender v. LG Elecs. U.S.A., Inc.*, No. C 09-02114, 2010 WL 889541, at *6 (N.D. Cal. Mar. 11, 2010) (holding that “[b]ased solely upon the facts alleged in the [First Amended Complaint], Bender’s infringement claim fails to provide a ‘plausible claim for relief’ under *Twombly* and *Iqbal*”). NS’s new noninfringement position above, NS Resp. at 19, is a *post hoc* attempt to supplement a deficient pleading. Courts “do not consider after-the-fact allegations in determining the sufficiency of . . . complaint[s].” *Frederico v. Home Depot*, 507 F.3d 188, 201 (3d Cir. 2007); *see also Penn. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (“[i]t is one thing to set forth theories in a brief; it is quite another to make proper allegations in a complaint.”); *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”).²

Second, on the substance, NS’s briefing discussion is insufficient even if considered in conjunction with the Amended Complaint, which asks for a ruling of *both* direct and indirect infringement. *See* D.I. 39, ¶ 89. However, the Amended Complaint does not allege sufficient facts

² *Cold Spring Granite Co. v. Matthews Int’l Co.*, No. 10-4272, 2011 WL 4549417, at *4 (D. Minn. June 1, 2011), cited by NS, is distinguishable. There the “Amended Complaint [wa]s not greatly detailed,” but the court declined to dismiss the noninfringement claim where both parties admitted the disputed “process did not have a more specific, industry-recognized name,” and “Plaintiff’s description of the process at the hearing affirms that this statement [within the operative complaint] identifies *with specificity* what is at issue in this declaratory judgment action.” *Id.* at *12.

relevant to either theory of noninfringement. *See id.*, ¶¶ 2, 77-89. NS’s arguments quoted above are limited to direct infringement of a method claim. *See* NS Resp. 19. NS does not allege in the Amended Complaint (or even its briefing) that it does not induce or contribute to the direct infringement of the UWA Patents by a third party. Notwithstanding that NS claims to “market and sell” its VILTEPSO® product, nothing in the Amended Complaint ties this allegation to any noninfringement assertion. D.I. 39, ¶ 77-89. Furthermore, NS does not even address the two compound patents for which DJ jurisdiction is also sought, *id.*, which demonstrates that it has no plausible noninfringement allegation to advance for these UWA Patents. *See supra* n.1. Thus, *Princeton Digital* applies, as does the *Wistron* case cited by NS, which dismissed noninfringement claims as insufficiently pled for similar reasons. *See Princeton Digital*, 2017 WL 239326, at *5; *Wistron Corp. v. Phillip M. Adams & Assocs., LLC*, No. C-10-4458 EMC, 2011 WL 1654466, at *12 (N.D. Cal. April 28, 2011). To the extent that NS is suggesting that it only had to identify “VILTEPSO” in its pleading without also identifying *how* the product allegedly does not infringe particular claims, *Wistron* does not support that proposition. *See id.* NS’s noninfringement arguments therefore fail to satisfy Rule 8(a). The Court should dismiss Claim II under Rule 12(b)(6), with prejudice due to futility of continued amendment. *See infra* § III.

II. THE COURT SHOULD DENY USE OF MATERIAL THAT VIOLATES THE MCA TO ESTABLISH DECLARATORY JUDGMENT JURISDICTION

A. The Court Should Reject NS’s Incorrect Interpretation of the MCA

NS does not dispute that its Amended Complaint describes alleged communications between the parties under the MCA. *See, e.g.*, NS Resp. at 2 (referring to “communications under the MCA”). NS’s primary argument for avoiding a violation of the MCA’s non-use provisions rests on a strained interpretation of the narrow exception in § 2.2, which does not apply here.

[REDACTED]

[REDACTED] NS Resp. at 6 (quoting D.I. 2, Ex. A [REDACTED] (emphasis added by NS)). NS continues that because it disclosed the MCA-protected materials “at least to support allegations relating to its contract claim (Claim I),” it can then use these allegations to support DJ jurisdiction for its unrelated patent claims (Claims II and III). *See* NS Resp. at 5. NS’s theory has numerous problems:

First, NS’s erroneously broad interpretation of [REDACTED] runs contrary to the purpose of the MCA as a whole to protect [REDACTED] [REDACTED] *See, e.g.,* Sarepta Br. 3-5, 13-15. NS’s position that asserting a contract dispute under Claim I opens the door to any and all uses of MCA-protected communications for DJ jurisdiction under Claims II and III makes no sense in context. The whole agreement [REDACTED]

[REDACTED]

[REDACTED]

D.I. 2, Ex. A at 1. [REDACTED]

[REDACTED]

³ [REDACTED]

[REDACTED]

[REDACTED]

³ *See* D.I. 2, [REDACTED]

[REDACTED]

██████████. *Id.* at ██████████
 ██████████ The ██████████
 ██████████ See
id. at ██████████

Second, NS suggests that “Sarepta argues that the plain and unambiguous language of ██████████ should be ignored” NS Resp. at 5 (citing Sarepta Br. at 14). Not so. Sarepta’s interpretation is fully supported by the plain and unambiguous language of the MCA. *See* Sarepta Br. at 14 (“This is not what the plain language provides.”); *id.* at 15 (“the MCA’s clear and unambiguous non-use provisions”). The plain and unambiguous language of *all* of MCA ██████████ speaks for itself, *see supra* n.3, but NS focuses on a few words out of context by emphasizing only a *portion* of a *phrase* within the larger sentence: ██████████

██████████ (emphasis by NS)). But NS ignores the
 ██████████
 ██████████ *Id.* The
 unrelated noninfringement and invalidity DJ actions ██████████

Third, by NS’s logic, the parties could make unrestricted use of any MCA-protected communications at any time ██████████

██████████ Such an approach is particularly unpersuasive here, where this Court has already held that NS is not likely to succeed on the merits of its interpretation of the MCA in Claim I. *See* D.I. 47 (denying preliminary injunction and finding that “Nippon Shinyaku has failed to persuade the Court that it is likely to succeed on the merits” of its contract interpretation). A strained reading

of the MCA in Claim I—in a self-described action to enforce a forum selection clause (*see* NS Resp. at 7)—should not serve as the basis for NS’s improper disclosures of MCA-protected information to establish DJ jurisdiction.

Finally, NS would have this Court accept that Claims II and III are, [REDACTED]

[REDACTED] NS Resp. at 7. This cannot be.

B. The MCA-Protected Communications Should Be Stricken or Otherwise Not Relied on for DJ Jurisdiction

NS argues that motions to strike are disfavored, NS Resp. at 4, but fails to address Sarepta’s cited cases making use of this remedy where confidential information is inappropriately imported into pleadings and other filings. Sarepta Br. at 7, 15 (collecting cases). Rule 12(f) *is* a permissible means of proceeding because these communications are immaterial and impertinent in context applied.

And NS’s assertion that there can be no prejudice because “the *very same information* found in the MCA Paragraphs and Non-MCA Paragraphs is properly pled to support [Claim I],” NS Resp. at 11, ignores that: (1) irrelevant confidential communications have now been prejudicially expanded into other contexts under NS’s flawed theory, so even if “disclosed” for Claim I does not mean these communication can be [REDACTED]

[REDACTED] MCA

[REDACTED] and (3) Claims II and III, which rely on the MCA-protected communications, seek to make Sarepta defend against costly DJ claims, which impermissibly target the UWA patents and deprive Sarepta of its bargained-for non-use rights at the core of the MCA. Sarepta Br. at 15.

On the last point, in contracting for the MCA's [REDACTED], Sarepta was following the procedure recommended by the Federal Circuit in *SanDisk*. See Sarepta Br. at 13 (“[T]he Federal Circuit stated that ‘[t]o avoid the risk of a declaratory judgment action,’ parties may seek ‘agreement to the terms of a suitable confidentiality agreement.’ Sarepta and NS did just that.”) (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375 n.1 (Fed. Cir. 2007)). NS has no adequate answer to *SanDisk*, *Osteotech*, and *Victor Reiling*, other than to say that it believes these decisions are inapplicable because [REDACTED]. See NS Resp. at 11 n.5 (discussing *SanDisk*; *Osteotech, Inc. v. Regeneration Techs., Inc.*, No. 3:06-cv-04FLW, 2008 WL 4449564, at *4 (D.N.J. Sept. 25, 2008); and *Victor G. Reiling Assocs. & Design Innovation, Inc. v. Fisher-Price, Inc.*, 407 F. Supp. 2d 401, 404 (D. Conn. 2006)). NS’s distinguishing of *SanDisk* relies on its flawed contract interpretation.

Even if the Court does not formally strike the challenged paragraphs, it can still disregard NS’s impermissible uses of this protected information and dismiss Claims II and III. See Sarepta Br. at 18 (“The Court should therefore *strike or otherwise disregard* Paragraphs 2 (second sentence), 11, 15-20, 78, 82-87, 91, and 95-100 of the Amended Complaint for violation of the MCA’s non-use provisions.”) (emphasis added). This would give effect to what *SanDisk*—and the parties—envisioned by ensuring that confidential discussions and exchanges of privileged information not be used to support patent actions. Regardless of whether Rule 12(f) is applied to prevent this harm to Sarepta, the Court can decide that the DJ claims should not proceed under the circumstances. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007) (recognizing discretion in exercise of DJ jurisdiction).

C. [REDACTED] Do Not Support DJ Jurisdiction

NS does not sufficiently plead a “substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment” on either noninfringement or invalidity.

MedImmune, 549 U.S. at 127; *see also Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335-36 (Fed. Cir. 2008). NS seeks to rely on [REDACTED]

[REDACTED] to support DJ jurisdiction. NS's arguments are unpersuasive:

[REDACTED] *See Sarepta Br.* at 17 (discussing MCA [REDACTED])

[REDACTED] This is distinct from items of [REDACTED], despite NS trying to blur these lines.

NS Resp. at 8. Again, the MCA [REDACTED]

[REDACTED] D.I. 2, Ex. A at 1. And NS [REDACTED]

In any event, [REDACTED], the allegations are of vague and innocuous conduct, such as: "Sarepta has taken affirmative action toward Nippon Shinyaku's VILTEPSO® product," and [REDACTED] and [REDACTED]

[REDACTED] *See D.I. 39, ¶¶ 15-17 (emphasis added).* [REDACTED]

[REDACTED]. *See id.*

Thus, NS provides no [REDACTED] to support any imminent or specific controversy.

Regarding the so-called [REDACTED], NS fails to respond to the fact [REDACTED]

[REDACTED] *Sarepta Br.* at [REDACTED]

17 (citing D.I. 54, Ex. A at 2 [REDACTED])

[REDACTED]; *id.*, Ex. B [REDACTED]

⁴ [REDACTED]

⁵ [REDACTED]

In sum, these alleged incidents taken alone or together, fail to plead a justiciable controversy or anything sufficiently concrete or immediate for DJ jurisdiction. If the Court declines to strike the paragraphs, it should still dismiss Claims II and III.

III. THE NS AMENDMENT REQUEST SHOULD BE DENIED FOR FUTILITY

NS suggests that it should be permitted to further amend its pleadings, relying on the liberal approach of the Third Circuit. NS Resp. at 20. But leave to amend may be withheld if (1) the moving party has demonstrated undue delay, bad faith, or dilatory motives; (2) it would be futile; or (3) it would prejudice the other party. *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 633 (D. Del. 2006). NS raises nothing to save Claims II or III—indeed, NS has added and already relinquished amended theories. Moreover, NS has doubled down in its Amended Complaint with more confidential communications. NS's prejudicial misuses of MCA-protected information should be brought to an end by a dismissal with prejudice of Claims II and III.

IV. CONCLUSION

For the reasons expressed, the Court should grant Sarepta's Rule 12 motion, with prejudice.

⁴ See also D.I. 2, Ex. A [REDACTED]

⁵ [REDACTED]

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